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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,350	01/27/2006	Tetsuro Tateishi	KUZ0028USNP	2515

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EXAMINER

PURDY, KYLE A

ART UNIT	PAPER NUMBER
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1609

MAIL DATE	DELIVERY MODE
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08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,350

Applicant(s)

TATEISHI ET AL.

Examiner

Kyle A. Purdy

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration:
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/27/2006</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant describes acrylic polymer as containing "substantially no alcoholic hydroxyl group in molecules" which is vague. What percentage of the copolymer contains alcoholic hydroxyl groups?

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1609

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6495159 to Hirano et al. in view of U.S. Patent No. 5866157 to Takayuso et al and Modamio et al., International Journal of Pharmaceutics 173 (1998) 141-148.

5. The prior art of Hirano relates to a percutaneous treatment device which has a drug release layer constituting a pressure-sensitive adhesive, an elastomeric polymer and percutaneous absorption promoters. The pressure-sensitive adhesive is an acrylic copolymer consisting of a meth(acrylic) alkyl ester and another functional monomer containing a carboxylic group which includes (meth)acrylic acid (i.e. vinyl acetate) (see column 6, lines 34-42). The notion of copolymerizing 2-ethylhexyl acrylate with vinyl acetate are taught at column 6, line 34 and in Example 14. Further, the idea of combining an acrylic copolymer with an elastomeric polymer is disclosed at column 5, line 43 to column 6, line 3. Specifically, Hirano discloses the use of polyisobutylene (available from Exxon Chemicals as trade name "Vistanex") and styrene-isoprene-styrene block copolymer (available from Japan Synthetic Rubber Co. as "JSR 5000").

Art Unit: 1609

The reference also teaches the use of aliphatic acids, aliphatic alcohols and esters of aliphatic acids having 7-20 carbon atoms at column 4, lines 42-56. Some specific examples of disclosed absorption promoters include lauryl alcohol, myristyl alcohol, glycerol monooleate and sorbitan monolaurate.

6. The differences between the prior art and the present application is that Hirano uses a serotonin-receptor antagonist and does not implement an organic acid or isopropyl myristate as a percutaneous absorption promoter. The prior art of Takayuso et al. describes the use of a patch formulation comprising organic acids, their corresponding salts (see column 2, line 62-66) and isopropyl myristate (see column 5, line 11) which are implemented to improve the absorption properties of the physiologically active substance (see column 2, line 62-66).

7. Modamo teaches a transdermal patch which contains bisoprolol hemifumarate as the physiological active substance. Additionally, the patch of Modamo has a penetration rate of $1.19 \pm 0.60 \text{ ug/hr/cm}^2$ (see abstract; Equation 6; Figure 1). Although the reported rate of penetration through the skin is less than that claimed the value reported by the reference approaches 3.0 ug/hr/cm^2 when three standard deviations are taken into account. Furthermore, Figure 1 shows the cumulative amount of bisoprolol with respect to time. However, by varying the thickness of the patch, the penetration rate of bisoprolol would arrive within the range of that claimed.

8. It appears that the units of the acrylic copolymer used in the adhesive are a matter of preference as both Hirano and Takayuso describe using copolymeric acrylic adhesives. Moreover, the invention of applying a patch for administering bisoprolol

Art Unit: 1609

renders the invention obvious. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the invention disclosed by Hirano with with organic acids and bisprolol as a physiologically active substance. Therefore, the combined teachings of Hirano in view of Takayuso and Modamo make prima facie obvious in the instant application.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached between 9AM to 5PM.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/566,350

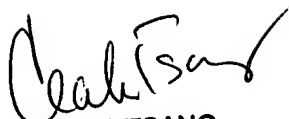
Page 6

Art Unit: 1609

Kyle A. Purdy

Art Unit 1609

July 11, 2007

A handwritten signature in black ink, appearing to read 'Cecilia Tsang', with a stylized flourish at the end.

CECILIA TSANG
SUPERVISORY PATENT EXAMINER